POLICY AND COMMUNICATIONS BULLETIN
THE CLINICAL CENTER

Medical Administrative Series

M89-1 (rev.) 15 July 1997

MANUAL TRANSMITTAL SHEET

SUBJECT: HIV Testing

1. Explanation of Material Transmitted: This issuance sets forth the Clinical Center's current policy on HIV Testing. The policy was initially approved by the NIH Human Research Review Panel on 8 December 1988, and by the CC Medical Board on 6 December 1988. The policy was reviewed by the Medical Executive Committee on 15 July 1997 and approved with no changes.

2. Material Superseded: MAS No. 89-1, dated 1 March 1989

3. Filing Instructions: Informed Consent Section

   Remove: No. 89-1, dated 1 March 1989

   Insert: No. M89-1 (rev.), dated 15 July 1997

DISTRIBUTION

Physicians, Dentists, and Other Practitioners Participating in Patient Care

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SUBJECT: HIV Testing

PURPOSE

This bulletin sets forth the Clinical Center (CC) policy on HIV antibody testing. Although this policy specifically addressed HIV antibody testing, it also applies to individuals who meet CDC surveillance criteria for AIDS, or who are considered HIV infected on the basis of an emerging technology that may not rely on antibodies.

POLICY

The CC policy requires informed consent before HIV testing for any reason. Tests may be conducted in the context of research, for clinical care of the patient, and in certain selected cases to obtain knowledge for the protection of patients and staff. Informed consent for HIV testing at the CC requires the following: 1) the informed consent of the patient before testing*; 2) prompt notification of patients about their test results (especially positive); 3) counseling (pre- and post-test) about the significance of the test results, the means to prevent the spread of the infection, and the responsibility of infected individuals to inform their sexual and/or needle-sharing partner(s) that they may be at risk for acquiring HIV; 4) informing CC patients that if they are found to be seropositive or to have AIDS and they are unable or unwilling to inform their partner(s) at risk, that it is PHS policy and thereby CC responsibility to attempt to assure that those partners have been notified. This policy is consonant with directives from the OPRR (1) and the PHS (2,3), and with recommendations issued by the Centers for Disease Control (CDC) (4,5,6).

IMPLEMENTATION OF POLICY

Notification of all patients about this CC policy will be done at the time of registration and/or admission. This notification process does not replace the responsibility of obtaining informed consent for testing and for assuring that the individual understands CC policy on HIV testing. This responsibility rests primarily with the attending physician or the appropriate designee.

A. HIV Testing in Research

1. The CC encourages HIV testing in all scientifically appropriate protocols. Examples include (but are not limited to): studies that involve the administration of immunosuppressive, cytotoxic, or immunomodulating substances; studies evaluating the use of therapeutic intervention(s) on the natural history of an illness; and studies that involve large volumes of blood, body fluids, or tissues that are obtained from patients. Knowledge of the patient's HIV serology in these settings is relevant to the study or the type of care delivered. Although clear scientific justification exists for excluding HIV-infected subjects from some protocols, exclusion on this basis alone shall not be universal. To allow for a case-by-case assessment of this issue, the CC encourages Institutional Review Boards (IRBs) to require protocols that exclude participation on the basis of HIV seropositivity to include the rationale for exclusion.

2. If HIV testing is part of a protocol, the protocol and consent document must include the following (or equivalent) language (8):

   "As part of your participation in this protocol, your blood will be tested for antibodies to the human immunodeficiency virus (HIV), the virus that causes AIDS. If you are found to have these antibodies, or if you have been diagnosed as having AIDS, you should be aware of the following Clinical Center policy:

   a. Your doctor will notify you promptly of the result.

   b. Your doctor and/or the Clinical Center HIV counselor will offer you, and current and/or ongoing sexual [Spouses are

generally considered current or ongoing sex partners.] or needle-sharing partner(s) whom you identify, information on the meaning of the test and how to prevent the spread of this infection.

c. Because HIV can be transmitted in several ways, it is important that you inform these partners that any or all may have been exposed to the HIV virus, and encourage them to be tested. If you request, the Clinical Center will assist you in notifying your current and/or ongoing partner(s), and arrange counseling through an HIV counselor.

d. In the event that you are unwilling or unable to notify any or all of these partners, the Clinical Center is responsible for attempting to assure that they have been made aware of their possible exposure to HIV. All reasonable attempts will be made to protect your identity. (For example, the partner(s) will be notified that they have been exposed to HIV without naming the individual who exposed them.)

Some of these notification and counseling procedures may be carried out through arrangements with, or referral to, local public health departments."

3. The PHS policy (3) does not affect testing protocols in which identifiers are not retained (i.e., anonymous testing).

B. <u>HIV Testing in Clinical Care</u>

1. The CC discourages mandatory HIV testing of patients (9), but encourages physicians to order HIV testing if there are clinical indications. Such indications include (but are not limited to): evaluation of manifestations consistent with HIV infection; circumstances in which knowledge of HIV serology may affect care (e.g., cytotoxic agents, immunomodulators); and instances in which the exposure risks of health care staff are increased (e.g., prolonged surgical procedures).

2. Decisions regarding the clinical indication for HIV testing should rest with the physicians providing clinical care.

3. HIV testing in clinical care should be done only after informed consent with documentation in the chart, ample opportunity for the patient to have read the information sheet, and time for patient discussion of the information sheet with the physician and/or HIV counselor.

   The physician should document the reasons for HIV testing in the patient's chart as well as documenting the patient's prior written consent, using the Clinical Center Consent Form for HIV Antibody Testing. If the patient is unable to consent, the most appropriate surrogate decision maker should be approached for permission (e.g., the next of kin or an authorized representative of the patient).

4. The CC will provide patients with an information sheet describing the significance of HIV testing. This information sheet will be given to all outpatient at the time of registration and to all inpatients at the time of admission. Copies of the information sheet will also be made available on the inpatient care units and in the clinics. This information sheet will provide details about the notification of test results, the meaning of positive, negative, or equivocal test results, limits of confidentiality of test results, the Clinical Center's policy on notification of partners, the means to be used to prevent the spread of this infection, and the availability of counseling.

C. Counseling CC Patients About the HIV Test

Because of the sensitivity of the topic and the skill required to perform counseling, an HIV counselor supported by a multi-disciplinary group (HIV Advisory Group) of consultants (bioethics, psychiatry, medical, pastoral care, social work) has been appointed to provide this important service for CC patients (AIDS, seropositive, seronegative, and indeterminate). Skilled counselor(s) will guarantee consistency of counseling and remove most (but clearly not all) the burden of counseling from the physician. Difficult cases should be referred to the HIV Advisory Group or to the Bioethics Office for assistance.

Footnotes

* The informed consent of the patient before testing for HIV antibodies is required in all cases except for occupational exposure of a health care worker. In these cases, all reasonable attempts should be made to obtain the informed consent of the patient before HIV testing of the blood. However, if the consent is not obtainable, it is justifiable to proceed with the test. Regardless of the outcome of the test, the patient should be informed of the results in accordance with CC policy.

1. Office of Protection from Research Risks, National Institutes of Health. Guidance for Institutional Review Boards for AIDS Studies. December 26, 1984.

2. "PHS Policy on Sex Partner Notification." Memo from Robert E. Windom, M.D. August 16, 1988.

3. "PHS Policy on Sex Partner Notification." Memo from Robert E. Windom, M.D. Pages 1 & 2. August 16, 1988.

4. CDC. Provisional Public Health Service inter-agency recommendations for screening donated blood and plasma for antibody to the virus causing acquired immunodeficiency syndrome. MMWR 1985(34): 1-5.

5. CDC. Recommendations for assisting in the prevention of perinatal transmission of human T-lymphotropic virus type III/lymphadenopathy-associated virus and acquired immunodeficiency syndrome. MMWR 1985(34): 721-726 and 731-732.

6. CDC. Recommendations for prevention of HIV transmission in health-care settings. MMWR 1987(36) supplement 2S: 1S-18S.